



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/519,135 | 08/15/2005 | Josette Maske | 2251/73607/JPW/MJW | 3638 |
| 23432 7590 08/29/2008 COOPER & DUNHAM, LLP 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036 | | | | |
| EXAMINER | | | | |
| KUMAR, VINOD | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1638 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 08/29/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,135

Applicant(s)

MASLE ET AL.

Examiner

VINOD KUMAR

Art Unit

1638

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8500)
- Paper No(s)/Mail Date 3/3/08
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on February 4, 2008 and March 3, 2008 are entered.

Status of objections and rejections

2. Claims 37-48 are pending. Claims 49 and 50 are newly added. Claims 1-36 are canceled. Newly added claims 49-50 falls within the scope of the elected invention. Accordingly, claims 37-48, and newly added claims 49-50 are examined on merits in the present Office action.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Objection to claims 37 and 42 have been withdrawn in light of claim amendment filed in the paper of March 3, 2008.

Election/restriction

5. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

6. Claims 43 and 48 are objected to because of the following informalities:
- Claim 43 is objected for lacking the recitation "plant" after "selected" in line 2.
- Claim 48 is objected for not reciting the full-form of "ERECTA" in line 3.
- Appropriate corrections are required.

These objections have been necessitated due to the claim amendments filed in the paper of March 3, 2008.

Claim Rejections - 35 USC § 112

7. Claims 37-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been necessitated by the Applicant's claim amendment filed in the paper of March 3, 2008.

Claims 37 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "transcribed to form a transcription product which is then expressed in the plant cells" which is confusing since it is unclear how "a transcription product" can be expressed again. A transcription product is itself an expression

product. A transcription product is supposed to under go translation to produce the protein. It is unclear what is intended.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "transcribed to form a transcription product which is then expressed in the plant" which is confusing since it is unclear how "a transcription product" can be expressed again. A transcription product is itself an expression product. A transcription product is supposed to under go translation to produce the protein. It is unclear what is intended.

Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "gene" which is confusing since the limitation "gene" implies that the structure comprises the coding sequence and the associated promoter, terminator and enhancer encoding regions are also a part of the structure (see The Federal Register, Vol. 66, No. 4, Friday, January 5, 2001 at page 1108, left column, Endnote 13). In the instant case, Applicants do not appear to describe such ERECTA gene associated nucleic acid sequences. It is suggested that "gene" be amended to "coding sequence". All subsequent recitations of "gene" are also rejected.

Claims 49 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "seeds from the selected plant", which is confusing, since it is unclear whether the seeds comprise the nucleic acid. It is suggested that the recitation, --, wherein said seeds comprise the nucleic acid-- be inserted at the end of claims.

Appropriate corrections/clarifications are required.

8. Claims 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has been necessitated by the Applicant's claim amendment filed in the paper of March 3, 2008.

The claim is broadly drawn to a method of obtaining a plant having enhanced transpiration comprising transformation of a culture of plant cells with an ERECTA gene.

The essential feature of claim 48 is an ERECTA gene from any source.

Specification describes a nucleic acid sequence (SEQ ID NO: 1) encoding ERECTA protein of SEQ ID NO: 2. The specification further describes functional complementation of an *Arabidopsis* mutant defective in ERECTA gene by transforming said mutant with a plant transformation vector comprising SEQ ID NO: 1. The transformed plant exhibited normal transpiration efficiency. See pages 74-77, example 8.

The specification does not describe structure of ERECTA genes isolated from diverse sources and genetic backgrounds. The breadth of the phrase "ERECTA genes" encompass diverse receptor protein kinases having extracellular LRRs (leucine rich repeats). The breadth of the phrase "ERECTA genes" also encompass coding sequences and the associated promoter, terminator and enhancer encoding regions of the Applicant's broadly claimed genus.

The specification does not describe the structure for the sequences encompassed by Applicant's broadly claimed genus, and thus their function of enhancing transpiration rate in a plant is unknown.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of functional activity (enhanced transpiration rate) of SEQ ID NO: 2.

State of the art (Shpak et al. Development, 131:1491-1501, 2004) suggests that ERECTA genes are receptor protein kinases involved in diverse cellular processes, such as, plant morphogenesis, architecture, including plant height (see abstract). Thus, Applicant's broadly claimed genus encompasses structures whose function is unrelated to the instantly claimed SEQ ID NO: 2.

The only species described in the specification is SEQ ID NO: 1, which encodes SEQ ID NO: 2.

Structures encompassed by the breadth of "ERECTA genes" are not described and thus their function of enhancing transpiration in a plant is unknown.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs: 1 and 2 are insufficient to describe the claimed genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written

Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102 & 103

9. Claims 37-48 remain, and newly added claims 49-50 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mitsukawa et al. (Japanese Patent Publication No. JP 09056382 A, Published March 4, 1997, translation enclosed) and evidenced by Masle et al. (Nature, 436:866-870, 2005) for the reasons of record as applied to claims stated in the Office action mailed on July 31, 2007.

Mitsukawa et al. disclose a method of producing a transgenic plant comprising transforming plant (*Arabidopsis*) cells with a plant transformation vector comprising a DNA construct having a gene which comprises a promoter (CaMV 35S) operably linked to a nucleotide sequence encoding the protein of accession No. AAW13408, which has 100% sequence identity to instant SEQ ID NO: 2. The reference further discloses expression of said nucleic acid sequence in the transformed cells, selection of transformed cells expressing the transgenic protein, and regenerating the transformed plant expressing the protein encoded by said nucleotide sequence. The reference also

discloses obtaining transgenic seeds from the transformed plant. See in particular, claims 1-6; paragraphs 0001-0055. The reference discloses all the active method steps of instantly claimed invention.

Although Mitsukawa et al. do not explicitly disclose enhanced transpiration efficiency in their transgenic plants, such a property would be inherent to the method of expressing the protein (accession no. AAW13408) in Mitsukawa et al. transgenic plant. The inherent property of enhanced transpiration efficiency is also evidenced by Masle et al. who disclose ERECTA gene encoding a protein having 100% sequence identity to Mitsukawa et al. protein, and wherein expression of said gene in a transgenic plant results in enhanced transpiration efficiency (see Masle et al. at page 436, abstract, figure 1; page 867, figure 2; page 436, figures 3-4). See MPEP 2111.02.

See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343,1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) where a claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase "rich in glucosinolates" helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently "rich in glucosinolates").

Also see *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

It is noted that instantly claimed invention encompasses a method step comprising selecting for a transgenic plant with enhanced transpiration efficiency phenotype compared to an untransformed plant. Neither the specification nor the prior art suggests that transgenic plant population expressing a polynucleotide encoding instant SEQ ID NO: 2 results in a significant proportion of transgenic plants which do not exhibit an increased transpiration efficiency phenotype. It would have been obvious to one of ordinary skill in the art to select for transgenic plant with increased transpiration efficiency (inherently associated property of polynucleotide sequence disclosed in the reference) because selection of a transgenic plant with a phenotype would have been the ultimate useful goal without any surprising or unexpected results.

It would have been obvious and within the scope of an ordinary skill in the art to have been motivated to practice the method of making transgenic plant of Mitsukawa et al., in an economically important food crop, such as, rice or corn in arriving at the instantly claimed invention with a reasonable of expectation of success.

It would have been obvious and within the scope of an ordinary skill in the art to transfer the transgene of Mitsukawa et al. into untransformed plants by cross hybridization of a wild-type plant with their transgenic plant. One of ordinary skill in the art would have been motivated to do so for the purpose of avoiding time-consuming and expensive method of transforming plant cells and obtaining transgenic plants thereof.

Applicant traversed the rejection in the paper filed on February 4, 2008 and March 3, 2008.

Applicant argues that Mitsukawa et al. teach the introduction of a nucleic acid to an *Arabidopsis* plant only. Due to this, Applicant argues that Mitsuka et al. cannot inherently anticipate claim 39 and 42 of the subject application. Applicant further argues that the prior art reference does not teach selecting for plants having enhanced transpiration efficiency (response, pg 10, lines 14-30).

Applicant's arguments have been carefully considered but are deemed to be unpersuasive.

It must be noted that although Mitsukawa et al. do not explicitly disclose transgenic plants of rice, sorghum, wheat or maize, however, it would have been obvious to practice the method of Mitsukawa et al. in a economically food crop including rice, sorghum, wheat or maize with a reasonable expectation of success.

It is further maintained that Mitsukawa et al. disclose a transgenic plant and a method of producing said transgenic plant comprising introducing and expressing a nucleotide sequence encoding the protein of accession No. AAW13408, which has 100% sequence identity to instant SEQ ID NO: 2.

It is further maintained that neither the specification nor the prior art suggests that transgenic plant population expressing a polynucleotide encoding instant SEQ ID NO: 2 results in a significant proportion of transgenic plants which do not exhibit an increased transpiration efficiency phenotype. It is therefore, maintained that would have been obvious to one of ordinary skill in the art to select for transgenic plant with increased transpiration efficiency because selection of a transgenic plant with a phenotype would have been the ultimate useful goal without any surprising or unexpected results.

Art Unit: 1638

Accordingly claims 37-48 remain and newly added claims 49-50 are rejected.

Conclusions

10. Claims 37-48 remain and newly added claims 49-50 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Vinod Kumar/

Examiner, Art Unit 1638